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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,703	10/31/2003	H. William Bosch	029318-0973	8369

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EXAMINER	
CLARK, SARA E	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
02/18/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/697,703	BOSCH ET AL.	
	Examiner	Art Unit	
	SARA E. CLARK	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-95* is/are pending in the application.

4a) Of the above claim(s) *32-35,39,41-43 and 45-95* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31,36-38,40 and 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/5/2009 and 1/26/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL REJECTION

Receipt is acknowledged of Applicants' Amendments and Remarks, filed 11/5/2009.

No claims have been amended, added, or canceled.

Claims 1-95 are pending.

Claims 32-35, 39, 41-43, and 45-95 stand withdrawn as drawn to a nonelected invention.

Thus, claims 1-31, 36-38, 40, and 44 now represent all claims currently pending and under consideration.

REQUEST FOR CONTINUED EXAMINATION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/5/2009 has been entered.

INFORMATION DISCLOSURE STATEMENT

The information disclosure statements (IDS) submitted on 11/5/2009 and 1/26/2010 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

MAINTAINED REJECTIONS

The following rejections are maintained from the previous Office Action dated 10/23/2009, on the ground that the references cited therein continue to read on the limitations of the amended claims.

Rejections under 35 USC §103

A. Claims 1-15 and 27-31 stand rejected under 35 U.S.C. 103(a) as being unpatentable over REINER et al. (USPN 5,711,961) in view of RYDE et al. (USPN 6,375,986).

The text of the rejection set forth in the Office Action dated 12/9/2008 is incorporated herein by reference.

B. Claims 1, 10-13, and 15-26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over REINER and RYDE in view of LIVERSIDGE et al. (USPN 5,552,160).

The text of the rejection set forth in the Office Action dated 12/9/2008 is incorporated herein by reference.

C. Claims 1 and 16-26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over REINER and RYDE in view of SINGH et al. (Analytical Profiles of Drug Substances and Excipients, Volume 28, 2001, p. 197-249) and BOSCH et al. (USPN 5,510,118).

The text of the rejection set forth in the Office Action dated 12/9/2008 is incorporated herein by reference.

D. Claims 1, 36-38, and 40 stand rejected under 35 U.S.C. 103(a) as being unpatentable over REINER and RYDE in view of SINGH et al. and MERCK (The Merck Index 12th ed. Merck & Co. 1996, p. 416-417).

The text of the rejection set forth in the Office Action dated 12/9/2008 is incorporated herein by reference.

E. Claims 1 and 44 stand rejected under 35 U.S.C. 103(a) as being unpatentable over REINER and RYDE in view of BUHL et al. (USPN 5,776,563).

The text of the rejection set forth in the Office Action dated 12/9/2008 is incorporated herein by reference.

RESPONSE TO ARGUMENTS

It is noted that Applicant's arguments dated 11/5/2009 (Remarks, pp. 26-32) are identical to Applicant's arguments dated 10/8/2009 (Remarks, pp. 26-32), which were addressed in the Advisory Action dated 10/23/2009.

In particular, Applicant contends that Reiner's teaching of nimesulide drug particles "in the micron size range" does not teach or suggest the limitation particles having an "effective average particle size of less than 2000 nm" (2 microns), as recited

by claim 1, but rather particles ranging in size from 1 to 999 microns. However, "in the micron size range" reasonably suggests particles in the size range of one micron, particularly considering that (a) the drug particles of Reiner are sprayed onto the surface of sugary microgranules having a size of 850 microns, so that by implication, the relative size of the drug particles must be much smaller than the sugary microgranules onto which they are coated, and (b) the plain meaning of "micronized" connotes "to pulverize, especially into particles a few micrometers [microns] in diameter." In addition, Ryde discloses nanoparticulate compositions in which the active agent has an effective average particle size of less than about one micron (col. 6, lines 23-51).

Applicant further contends that there is no rationale to combine Reiner and Ryde, because the two references are directed to unrelated technologies and could be combined to arrive at the claimed invention only by impermissible hindsight. However, both Reiner and Ryde disclose solid-dose nanoparticle pharmaceutical compositions formulated for oral administration of poorly soluble active agents. Improving a drug's pharmacokinetic profile, such as its dispersibility and bioavailability, is a common objective in the pharmaceutical arts, which can be achieved by making one or more of several well-known modifications. These include, for example, reducing particle size to increase surface area, and formulation with certain excipients to enhance the drug's solubility. Thus, optimizing the particle size and choice of excipient(s) involves routine experimentation rather than an inventive step, particularly when the adjustments have been attempted and proven useful in similar drug formulations, as in Reiner and Ryde.

Finally, Applicant contends that modifying Reiner in view of Ryde would destroy the intended purpose of a component in Reiner, or alternatively, that there is no teaching in either of the cited references that micron-sized drug particles need surface stabilizers to prevent aggregation. However, Ryde teaches that a frequent problem in prior art nanoparticulate compositions was that upon administration to a mammal, the nanoparticulate composition fails to redisperse and forms clumps or agglomerated drug particles, reducing the drug's bioavailability (col. 5, lines 31-45), and that an improvement taught in some prior art patents is the usefulness of polymeric surface stabilizers for nanoparticulate compositions (col. 3, lines 39-53).

In light of the foregoing, no impermissible hindsight is required to arrive at a pharmaceutical composition comprising nimesulide particles having an average effective particle size of less than 2 microns with at least one surface stabilizer adsorbed onto the surface thereof, as recited by the instant claims. Hence, the rejections of claims 1-31, 36-38, 40, and 44 are maintained.

CONCLUSION

No claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued

examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARA E. CLARK whose telephone number is (571) 270-7672. The examiner can normally be reached on Mon - Thu, 7:30 am - 5:00 pm (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SARA E. CLARK/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612